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52

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/469,738	12/21/1999	JOSEPH J. CHANG	056301.P478	5325

7590

02/10/2004

WOOD, HERRON AND EVANS  
2700 CAREW TOWER  
CINCINNATI, OH 45202

EXAMINER
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HAYES, MICHAEL J

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 02/10/2004

24

Please find below and/or attached an Office communication concerning this application or proceeding.

2.1

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/469,738		CHANG, JOSEPH J.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Michael J Hayes		3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 November 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 October 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the moveable member coupled to the blunting member and engaging the outer surface of the introducer sheath which advances the blunting member when the sheath is removed must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Specification/Drawings***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: there is no antecedent basis for “moveable member” in the specification.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

Claims 14-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed

invention. New matter appears to be recited in claim 14 which recites a moveable member coupled to the blunting member and engaging an outer surface of the introducer sheath where the moveable member advances the blunting member when the sheath is removed. The advancing of the blunting member with such a moveable member was not previously described in the application.

Claims 14-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is not enabling for how the blunting member is moved relative to the needle. The drawings and specification teach that the blunting member is secured to the housing 67 via securing member 75/77 and the needle 18 is attached to the housing 67 at the distal end of the housing 67. See figs. 1, 3, 4-6. Since both the needle and the blunting member are coupled to the housing and there is no separate moveable member separately accessible from the housing attached to the blunting member it appears that the needle and blunting member will move together and not respective to each other.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over GOMEZ (EP 0 630 661) in view of SAHI (U. S. Patent No. 5,009,642) and CHANG (U. S. Patent No. EP 0 353 905). Gomez discloses a catheter unit including an introducer sheath 72, needle 76, and flash chamber 78 having a flash plug 80. Gomez does not disclose a hollow blunting member fitting within the needle bore, a porosity for the flash plug, or a moveable member coupled to a blunting member and engaging an outer surface of the introducer sheath for advancing the blunting member. Sahi teaches the use of a hollow blunting member to protect against needle injury and to communicate with a flash chamber where a moveable member 22 is coupled to the blunting member and engages the outer surface (i.e., surface of 42b) of the introducer sheath 40 (Figs. 2-5). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the blunting member and moveable member of Sahi in the device of Gomez in order to provide safe and accurate use of the medical device to prevent accidental injury due to the needle. Chang teaches the use of a UHMWPE flash plug with various porosities within the range of 35-55% (pg. 4, Table; claim 9) to provide for rapid filling of the flash chamber and thorough sterilization. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the porosities as taught by Chang in the catheter unit of Gomez and Sahi in order to provide a sterilizable device with efficient flash chamber.

#### ***Response to Arguments***

Applicant argues that the drawings show portion 77 as it rests in housing 67 to engage introducer 15. The examiner disagrees and can find no drawing that shows this arrangement. Applicant's reliance on possible constructs are not convincing. There is no figure that shows a

moveable member coupled to the blunting member and engaging the outer surface of the introducer sheath which advances the blunting member when the sheath is removed.

Furthermore, this relationship was not described in the application as filed.

Applicant argues that “movable member” is supported in the specification because it is inherent in the description of securing member 75 that it moves. This argument does not rectify the antecedent problem. Applicant should amend the specification to identify the movable member, using these terms with an associated numerical label in order to make clear what element is the “movable member.”

Applicant argues that a “securing member” should not be interpreted as performing a securing function because the securing member holds blunting member 65 in position. Applicant further states that securing member 75 is described as a hook to anchor the blunting member in position. (citing col. 6, lines 22-23) (found on page 6, second paragraph, of response received 11/21/03 (Paper No. 21). The examiner maintains the interpretation of “securing member” as one that secures or anchors the blunting member in position.

Applicant did not address the new matter rejection by pointing to language contained in the originally filed application that would supply evidence that he had possession of a moveable member coupled to the blunting member and engaging an outer surface of the introducer sheath where the moveable member advances the blunting member when the sheath is removed at the time of filing. There is no previously described relationship between the sheath and the movable member or advancement of the blunting member due to the sheath removal. This rejection is maintained.

Applicant argues that Sahi does not teach a movable member or advancing a blunting member to a distal position when a sheath is removed. The examiner disagrees and refers Applicant to movable member 22 as shown in Figs. 2-5 and related text. These figs are described, particularly with respect to movable member 22, at col. 8, lines 5-41. The movement of the member 22 is discussed with respect to the blunting member that is extended.


***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler, can be contacted at (703) 308-3552. The fax number for submitting official papers is (703) 872-9306.

mjh  
5 February 2004

  
**MICHAEL J. HAYES**  
**PRIMARY EXAMINER**